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In the Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA, PETITIONER

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

REPLY BRIEF FOR THE UNITED STATES

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1. The Federal Food, Drug and Cosmetic Act does not create a "status" offense.

1. Respondent Park and the amici contend that the government seeks to base Park's criminal responsibility "solely on Park's status as chief executive officer of the corporation."[1] Some of the amici characterize this asserted theory as the imposition of "vicarious liability"[2] and another ar-

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[1]Park Br., p. 21; see Synthetic Organic Chemical Manufacturers Association ("SOCMA") Br., p. 15; National Canners Association ("Canners") Br., pp. 21-22; National Association of Food Chains ("Food Chains") Br., pp. 13, 16; Grocery Manufacturers of America ("GMA") Br., pp. 4, 17.

[2]SOCMA Br., pp. 8, 15; Food Chains Br., pp. 9, 13 n. 2, 16; GMA Br., p. 3.

gues that this alleged approach improperly dispenses with "*actus rea*" or "causation."[3]

These generalized claims fail to recognize the unique character and special importance of the pure food and drug laws. This Court has long recognized that "the public interest in the purity of its food [and drugs] is so great as to warrant the imposition of the highest standard of care on distributors—in fact an absolute standard which will not hear the distributor's plea as to the amount of care he has used." *Smith* v. *California*, 361 U.S. 147, 152. "In the interest of the larger good [the Food, Drug and Cosmetic Act of 1938] puts the burden of acting at hazard upon a person otherwise innocent but standing in a responsible relation to a public danger." *United States* v. *Dotterweich*, 320 U.S. 277, 281. The 1938 Act thus imposes an affirmative duty on those "standing in a responsible relation to a public danger": it requires them to seek out and to prevent insanitary conditions. In this manner "the distributors of food [are made] the strictest censors of their merchandise * * *." *Smith* v. *California, supra*, 361 U.S. at 152.

Once this duty to exercise "the highest standard of care"—which Park and the amici do not discuss—is recognized, it is evident that the 1938 Act does not punish "status" or impose "vicarious liability." The corporate officer in a "responsible relation to a public danger" has a *personal* affirmative duty to become informed about, and a duty to act to prevent, conditions that violate the Act. In making him criminally responsible for his failure to discharge that duty, the law punishes his *own* failure to act; it does not make him "vicariously" liable for the act of another. It punishes "neglect where the law requires care, or inaction where it imposes a duty." *Morissette* v. *United States*, 342 U.S. 246, 255.

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[3]Canners Br., pp. 16, 21.

Similarly the element of "causation" urged by Park (Br., p. 24) and Canners (Br., p. 21) inheres in the failure of the responsible corporate official to seek out and prevent insanitary conditions that could have been prevented. The legislative history of the 1938 Act—our view of which has not been seriously disputed—shows that the 1938 Act punishes acts of omission as well as willful violations. See United States Br., pp. 27-28. Thus the Senate report on S. 2800 spoke of the penalties reserved for "those who violate the law through inadvertence, carelessness, or negligence" (S. Rep. No. 493, 73d Cong., 2d Sess., p. 20).[4]

The 1938 Act does not create "status" offenses. "Status" offenses improperly permit the imposition of criminal penalties "upon a person for being in a condition he is powerless to change." *Powell* v. *Texas*, 392 U.S. 514, 567 (Fortas, J., dissenting). In contrast, the criminal liabilities created by the 1938 Act rest squarely upon a corporate official's *power* to affect the prohibited condition. Responsible corporate officials "have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce." *United States* v. *Dotterweich, supra*, 320 U.S. at 285. Moreover, a claim by the official that he is

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[4]While Park and some of the amici acknowledge the possibility of liability based on failures to act, they suggest a standard of gross negligence (Park Br., pp. 25-26; Food Chains Br., pp. 13-15; GMA Br., p. 11). Yet in 1948 Congress refused to adopt an amendment to Section 303(a), passed by the Senate, which would have imposed criminal liability only for violations committed "willfully or as a result of gross negligence " (see United States Br., pp. 29-30.)

"powerless" may "be raised defensively at a trial on the merits." *United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91.[5]

2. The charge did not require the jury to find Park guilty solely on the basis of his status.

Park (Br., p. 21), by isolating one sentence in the jury instructions, argues that the entire charge amounts to a direction of a verdict based on his status as chief executive officer of Acme. However, "a single instruction to a jury may not be judged in artificial isolation, but must be viewed in the context of the overall charge." *Cupp* v. *Naughten*, 414 U.S. 141, 146-147; *Boyd* v. *United States*, 271 U.S. 104, 107.

When the charge is viewed as a whole, it is clear that the jury was not directed to find Park guilty solely on the basis of his status as chief executive. To the contrary, the trial judge specifically admonished the jury that, "the fact that the Defendant is [president] and is a chief executive officer of the Acme Markets does not require a finding of guilt." Moreover, the jury was specifically asked to determine whether "the individual had a responsible relation to the situation," and, later, whether he "had a responsible relationship to the issue [which] * * * is, in this case, whether the Defendant * * * had a position of authority and responsibility in the situation out of which these charges arose." (For complete instruction, see United States Br., pp. 10-11.) A reading of the entire instruction indicates that the jury was specifically advised to consider

[5]A "status" offense may also involve "punishment for a mere propensity, a desire to commit an offense; the mental element is not simply one part of the crime but may constitute all of it." *Powell* v. *Texas, supra*, 392 U.S. at 543 (opinion of Black, J.). Obviously the criminal liability created by the 1938 Act for discrete instances of food contamination punishes neither a "propensity" nor a "condition" of the responsible corporate official.

Park's relationship to the insanitary conditions that formed the basis of the information.

3. The charge was consistent with this Court's holding in Dotterweich.

In an attempt to narrow the effect of this Court's ruling in *Dotterweich*, Park states (Br., p. 21) that no significant effort was made by Dotterweich at trial to establish a lack of personal liability. The record in *Dotterweich* does not support this assertion. Dotterweich, like Park, made every attempt to deny his personal involvement in the violative shipments. He testified, *inter alia*, that "[t]he company is almost automatic in its operation" and that, as a result of health problems, "I do so little now that I leave Mr. Munn in charge." Munn testified that he (and not Dotterweich) had "taken complete charge of the receiving and shipping end" of the business, that he created the system for shipping drugs and that he (and not Dotterweich) supervised the shipments in question.[6] In fact, Munn testified that some "third person" could have made the violative shipment (Record on Appeal, No. 5, O.T. 1943, pp. 29, 30-32, 35, 129, 143 and 144; see also United States Br., p. 19, n. 8).

Park also states (Br., p. 18) that the issue before this Court in *Dotterweich* was whether an individual employed by a corporation could "ever" be liable under the Act. But Dotterweich repeatedly and continuously argued to this Court that there "had to be some act * * *," and that a second trial was necessary to fully explore "the question of fact as to whether [he] had any connection with [the] shipment" (see Memorandum in Opposition to Petition for a Writ of Certiorari, No. 5, O.T. 1943, p. 5-6; Brief for

[6]Compare Park's testimony, at A. 55, to the effect that while he is ultimately responsible for the entire operation of the company, he "would hold Mr. McCahan responsible" for any failure in Baltimore.

Respondent, No. 5, O.T. 1943, p. 5 and Point Two, "The respondent was the agent of the defendant corporation and some wrongful act on his part must be shown," p. 15; and Petition for Rehearing, No. 5, O.T. 1943, p. 6).

In short, the arguments advanced by Park today were squarely before this Court more than thirty years ago. Park, like Dotterweich, is guilty not solely because of his title, but because he had the duty, the power and the authority to discover and prevent the violation in the first instance, and because he failed to do so.

4. Responsibility under the 1938 Act does not depend on knowledge.

Park argues (Br., pp. 27-32) that the statement of the court of appeals in *United States* v. *Abbott Laboratories*, 505 F. 2d 565, 573, to the effect that " '[r]esponsibility' * * * [under the 1938 Act] depends upon knowledge * * * ," merely reiterated the government's argument on appeal in that case. In *Abbott Laboratories*, a prosecution under the 1938 Act for distributing misbranded and adulterated drugs, the district court had dismissed the indictment because it found that the prosecutor had prejudiced the grand jury by inquiring of grand jury witnesses whether they were aware of reports of deaths resulting from contaminated intravenous solutions made by Abbott Laboratories. 369 F. Supp. 1396, 1405 (E.D.N.C.).

In reversing the district court's dismissal of the indictment, the court of appeals stated that the evidence in question was relevant to establish criminal responsibility under the Act because " '[r]esponsibility' * * * depends upon knowledge * * *." However, contrary to Park's assertion (Br., pp. 27-30), the government did not argue that an individual's criminal responsibility under the Act depends upon his knowledge of a violation of the Act.

Rather, the government argued that evidence that persons had died as a result of using Abbott drugs was relevant to the grand jury's investigation of possible violations of the Act by Abbott and its employees.

The evidence was relevant because one possible violation of the Act within the scope of the grand jury's investigation was whether the Abbott drugs were misbranded within the meaning of Section 502(j) of the Act, 21 U.S.C. 352(j).[7] That Section states that a drug is misbranded "[i]f it is dangerous to health." Obviously, evidence that death or illness had resulted from the use of Abbott drugs was relevant to establish a danger to health. Moreover, the grand jury could properly consider the reports of death, the knowledge that Abbott officials had of the reports and the actions they took in the light of those reports, as a means of illuminating their roles in the company and in the distribution of the drugs.

It does not follow, however, that any given official's responsibility is dependent on his knowledge. Indeed, *United States* v. *Dotterweich*, *supra*, 320 U.S. at 281, makes clear that the 1938 Act "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing." The fact that this evidence was relevant in determining whether the Act had been violated and in assessing individual criminal responsibility under the Act does not make it a necessary element of the government's case in a criminal prosecution.

5. The fact that the FDA does not prosecute minor violations of the law should not be used to lower the standard of care required of distributors.

Park (Br., pp. 32-33) and Canners (Br., pp. 33-34) argue that the Act would not be weakened by a lower standard of liability, because the FDA does not prose-

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[7]Park is not charged with distributing a misbranded drug or device.

cute for every violation of the Act and often awaits a second or subsequent offense showing a continuing violation before instituting prosecution.[8] But the success of the FDA's informal enforcement procedures is, of course, dependent on the availability of the law's criminal sanctions when needed.

In any event, this contention fails to recognize the distinction between the statutory standard for criminal liability, and the prosecutorial discretion lodged in a law enforcement agency. In the 1938 Act, Congress established perhaps the highest standard of care ever imposed by law, because of the obvious critical importance of safe and wholesome food and drugs to the public health and welfare. At the same time, Congress recognized in Section 306 of the Act the essential role of prosecutorial discretion in enforcing that high standard of care. (See United States Br., p. 30-32.) Thus, the statutory scheme recognizes that, even though not all violators will be prosecuted, the strong deterrent effect of strict criminal liability still represents a major statutory enforcement mechanism.

None of the opposing briefs contends that the FDA has used its prosecutorial discretion arbitrarily or unwisely. The recent study sponsored by the industry-financed Food and Drug Law Institute forthrightly concludes that "our limited survey of unreported cases does not raise serious questions of the abuse of the [*Dotterweich*] doctrine." O'Keefe and Shapiro, *Personal Criminal Liability Under The Federal Food, Drug, and Cosmetic Act: The Dotterweich Doctrine*, 30 Food Drug Cosmetic L.J. 5, 43 (1975).

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[8]The FDA uses informal procedures and civil actions to enforce the law far more often than it uses criminal action. For example, in fiscal year 1973-1974 the FDA made 33,511 establishment inspections, issued 1,195 formal regulatory letters requiring compliance with the Act, handled 881 violations by voluntary recalls of the products, and recommended to United States Attorneys 419 seizure actions, 21 injunction actions, and 88 criminal actions.

6. Neither alternative methods of enforcement nor a lower standard of care are adequate to assure compliance with the 1938 Act.

Some of the amici (Food Chains Br., pp. 17-24; Canners Br., pp. 24-26, 29-34) contend that a lower standard of care is appropriate because the FDA has other enforcement techniques and because a lower standard will, paradoxically, result in better compliance with the law.[9]

Seizure and injunction, the other judicial remedies contained in the Act, only prevent future violations of the law. Absent the availability of strict criminal sanctions, food and drug manufacturers would have no incentive to seek out and prevent violations, since they could simply wait for an FDA inspector to find a violation before doing anything about it.[10]

The argument of one amicus (Canners Br., p. 25) that criminal responsibility should be limited to consequences known to, or reasonably foreseen by, the corporate official is premised on its refusal (see p. 2, *supra*) to acknowledge the statutory duty of a food distributor to seek out and prevent violations. Obviously a recognition of this affirmative duty is the first step toward better compliance with the 1938 Act. Conversely a lower standard of care, predicated on a refusal to recognize that duty, will inevitably lead to more widespread violations.

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[9]Canners (Br., pp. 3-6, 32-33) takes inherently inconsistent positions on this matter. It first contends that extensive delegation of authority is essential in modern industrial management, and then inexplicably argues that corporate officers could not isolate themselves from potential violations of the Act without becoming unable to function effectively in their executive positions.

[10]The FDA has only 1,000 inspectors who dedicate half their time to food inspection, to monitor more than 70,000 food manufacturing and warehousing establishments, 275,000 retail food stores, and 600,000 other food service establishments (principally restaurants).

The FDA's experience during the second half of the 1960's proved that only vigorous enforcement of the law, by all available means, will bring about compliance. For approximately a five-year period, the FDA reordered its priorities to emphasize the regulation of drugs and to reduce its surveillance of food sanitation. In this relatively short period of time there was a substantial deterioration in the sanitary condition of the food industry as a whole, as found in the 1972 GAO Report (see United States Br., p. 36). As a result of that report, Congress doubled the FDA's resources for food sanitation enforcement. In the past year, after this increase in enforcement, the FDA has found noticeable improvement in the sanitation conditions of food establishments.[11]

Respectfully submitted.

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[11]If the lower standard for criminal enforcement advocated by Park and the amici were adopted, the admission at trial of all evidence of prior violations should be permitted in order to establish the requisite "wrongful action," even if such action occurred outside the applicable statute of limitations. In the instant case, for example, not only should the letter and other pertinent evidence relating to the earlier violations that occurred at the Philadelphia warehouse be admissible, but also any earlier violative conditions should be admissible, to establish corporate and individual awareness, and thus the "wrongful action" urged by Park and the amici.